

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: GLENN J. GORMLEY et al.  
Serial No.: To be Assigned Case No.: 19109DE  
Filed: December 7, 2001  
For: TRANSDERMAL TREATMENT WITH 5-ALPHA  
REDUCTASE INHIBITORS (as amended)

Art Unit:

1614

**EXPRESS MAIL CERTIFICATE**

DATE OF DEPOSIT DECEMBER 7, 2001

EXAMINER: EL 523708472US

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Assistant Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT  
TO ACCOMPANY A 37 CFR 1.53(b) FILING

Sir:

The preliminary amendment is being sent to accompany a new divisional application for filing under 37 CFR 1.53(b). Entry of the following amendment is respectfully requested.

IN THE SPECIFICATION:

At p. 1, in the section labeled "TITLE OF THE INVENTION", delete the title "METHOD OF TREATING ANDROGENIC ALOPECIA WITH 5-ALPHA REDUCTASE INHIBITORS", and substitute therefor the new title - TRANSDERMAL TREATMENT WITH 5-ALPHA REDUCTASE INHIBITORS --.

At p. 1, lines 9-10, delete the paragraph that reads "This application is a continuation-in-part of S.N. 08/138,520 filed October 15, 1993." and replace it with the following new paragraph:

-- CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. SN 09/699,906, filed October 30, 2000; which in turn is a divisional of U.S. SN 09/448,930, filed November 24, 1999, and issued on January 16, 2001, as U.S. Patent 6,174,892; which in turn was a divisional of U.S. SN 09/135,512, filed March 20, 1998, presently abandoned; which in turn was a divisional of U.S. SN 08/601,497, filed February 14, 1996, which issued on June 2, 1998, as U.S. Patent 5,760,046, which in turn was a continuation of U.S. SN 08/214,905, filed March 17, 1994, which issued on August 20, 1996, as U.S. Patent 5,547,957, which in turn was a continuation-in-part of U.S. SN 08/138,520, filed October 15, 1993, now abandoned. --

At p. 19, in the section labeled "TITLE OF THE INVENTION", delete the title "METHOD OF TREATING ANDROGENIC ALOPECIA WITH 5-ALPHA REDUCTASE INHIBITORS", and substitute therefor the new title -- TRANSDERMAL TREATMENT WITH 5-ALPHA REDUCTASE INHIBITORS --.

IN THE CLAIMS:

Cancel Claims 1-27.

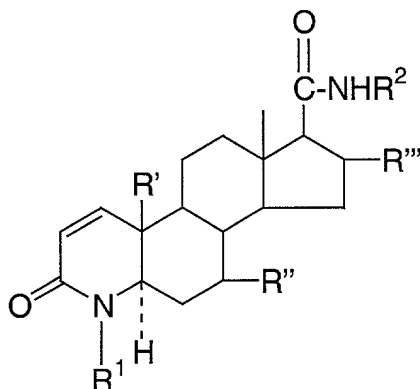
Add new Claims 28-37:

28. (New) A method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

29. (New) The method according to Claim 28, wherein androgenic alopecia is male pattern baldness.

30. (New) The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

31. (New) The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula I:



I

or a pharmaceutically acceptable salt thereof wherein:

$R^1$  is hydrogen, methyl or ethyl;

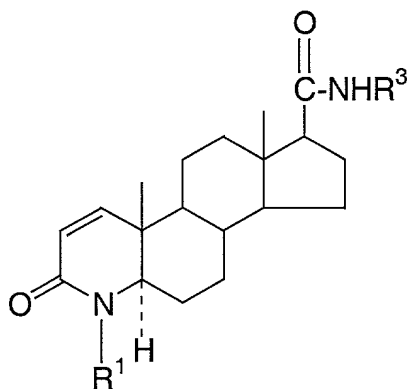
$R^2$  is a hydrocarbon radical selected from straight and branched chain alkyl of from 1-12 carbons or monocyclic aryl optionally containing 1 or more lower alkyl substituents of from 1-2 carbon atoms and/or 1 or more halogen (Cl, F or Br) substituents;

$R'$  is hydrogen or methyl;

$R''$  is hydrogen or  $\beta$ -methyl; and

$R'''$  is hydrogen,  $\alpha$ -methyl or  $\beta$ -methyl.

32. (New) The method according to Claim 28, wherein the 5 $\alpha$ -reductase 2 inhibitor has the structural formula II:



II

or a pharmaceutically acceptable salt thereof, wherein:

$R^1$  is hydrogen or methyl; and

$R^3$  is branched chain alkyl of from 4 to 8 carbons.

33. (New) A method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of  $17\beta$ -(N-tert-butylcarbamoyl)-4-aza- $5\alpha$ -androst-1-ene-3-one.

34. (New) The method of Claim 33 wherein androgenic alopecia is male pattern baldness.

35. (New) The method according to Claim 33, wherein the  $17\beta$ -(N-tert-butylcarbamoyl)-4-aza- $5\alpha$ -androst-1-ene-3-one inhibitor is transdermally administered by a transdermal skin patch.

36. (New) A transdermal skin patch comprising a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor.

37. (New) The transdermal skin patch according to Claim 35 wherein the 5alpha-reductase 2 inhibitor is  $17\beta$ -(N-tert-butylcarbamoyl)-4-aza- $5\alpha$ -androst-1-ene-3-one.

#### REMARKS

Consideration of the present application in light of the preliminary amendments above is respectfully requested. Original Claims 1 to 27 have been canceled and new Claims 28 to 37 have been added. Presently, Claims 28 to 37 are pending in the present application.

Applicants have amended the title of the invention to accurately reflect the claimed subject matter of the present divisional application.

Applicants have also amended the specification to reflect the proper ancestry of the present divisional application.

The "transdermal" aspect of the transdermal administration of the 5alpha-reductase 2 inhibitors according to the present invention, for the treatment of androgenic alopecia, and particularly male pattern baldness, as well as transdermal skin patches containing these 5alpha-reductase 2 inhibitors find particular support in the specification as originally filed at page 6, line 32 to page 7, line 2. Other limitations of the claims find support in the original claims as filed, as well as throughout the description of the invention.


Applicants submit that the amendments above do not add new matter to the present application.

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In summary, Applicants respectfully request examination, allowance and passage to issue of the present claims.

Respectfully submitted,

By



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/cdf  
Enclosures

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